REMARKS

The Examiner has rejected claims 1-7, 9-15 and 16-36 under 35 U.S.C. § 102(e) as being clearly anticipated by McDewitt et al., United States Patent Application No. 2003/0064422. In addition, the Examiner has rejected claims 1-5, 7, 9-11, 17-21, 24-31 and 33-36 under 35 U.S.C. § 102(b) as being clearly anticipated by Tiru et al., US Patent No. 4,149, 852 and has rejected claims 1-7, 9-15 and 16-36 under 35 U.S.C. § 103(a) as being unpatentable over Beebe et al., U.S. Patent No. 6,488,872. In view of the foregoing, applicant has amended the present application to more particularly define the invention for which protection is sought. As such, reconsideration of the Examiner's rejections is respectfully requested.

Initially, it is noted that applicant has cancelled claims 1-9. Referring to claims 10, a method for monitoring the environment within a microfluidic device. The method includes the steps of immobilizing a monitor structure in a channel of a microfluidic device and passing the fluid over the monitor structure. The monitor structure generates a visual display independent of the size of the monitor structure in response to a parameter of fluid having a predetermined value. The monitored structure is immobilized in the channel by mixing a dye in a pre-polymer mixture and providing the same as a pregel. The pregel is injected into the channel of the microfluidic device and polymerized to form the monitor structure. As hereinafter decribed, nothing in any of the cited references shows or suggests the mixing of a dye into a pre-polymer mixture, injecting that mixture into a channel of a microfluidic device, and polymerizing the mixture to form a monitor structure. Such a methodology is entirely absent from the cited references.

The McDevitt '422 application discloses a method and system for selecting and transmitting chemical information. Referring to paragraphs 0123, 0127 and 0145, the '422 application contemplates the use of particles that swell in response to contact with a fluid. Paragraph 0154 discloses a receptor bound to a polymer resin created particle that senses the changes in pH in the fluid sample. However, nothing in the '422 application suggests the mixing

of a dye into a pre-polymer mixture, injecting that mixture into a channel of a microfluidic device, and polymerizing the mixture to form a monitor structure. Such a methodology is entirely absent from the '422 application. Consequently, it is believed that claim 10 clearly defines over the '422 application.

The Tiru et al. '852 patent discloses a pH indicator composition having controlled change of color at selected sub-freezing temperatures. The composition includes a pH indicator and a control agent added to a buffer solution. When frozen, the composition is useful in a color change thermometer. It is noted, however, that the '852 patent does not disclose a pre-polymer mixture, the mixing of a dye into a pre-polymer mixture, injecting that mixture into a channel of a microfluidic device, and polymerizing the mixture to form a monitor structure, as required by independent claim 10. Such steps are entirely absent from the '852 patent. Hence, it is believed that claim 10 clearly defines over the '852 patent.

The Beebe et al. '872 patent is directed to a method of fabricating a microfluidic device. Referring to Figs. 1a–1b of the '872 patent, a detection device is provided for detecting a component in the biological fluid or other liquid media is provided. The device 100 contains a responsive hydrogel 102 in microchannel 104. Responsive hydrogel 102 contracts upon exposure to an analyte of interest, thereby allowing component A in a microchannel 108 to flow to a chamber 106 and mix with a component B in order to produce a detectable change, for example, a color change in chamber 106. The color change provides a macroscale response to a microscale event, i.e., contact of the analyte of interest with responsive hydrogel 102.

Heretofore, the Examiner has suggested that page 8, line 18 + of the Beebe et al., '872 patent teaches a pH sensitive polymer mixture hydrogel. As such, in the Examiner's opinion, such a pH sensitive hydrogel reads on the claimed subject matter. However, nothing in the '872 patent shows or suggests the methodology of claim 10, namely, the mixing of a dye into a pre-polymer mixture, injecting that mixture into a channel of a microfluidic device, and polymerizing

the mixture to form a monitor structure. More specifically, there is nothing in the '872 patent that shows or suggests immobilizing a dye within a hydrogel. The suggestion of such a methodology is entirely absent from the cited references. As heretofore described, the '872 patent merely disclosed a device wherein a hydrogel sensor actuator changes size in response to a change in pH.

Since the '422 application and the '852 patent do not disclose each and every limitation of independent claim 10, it is believed that claim 10 is not anticipated by the cited references. Further, since there is no teaching or suggestion in the '872 patent to immobilize a dye within a hydrogel as required by independent claim 10, applicant believes that claim 10 clearly defines over the '872 patent. Consequently, it is believed that independent claim 10 is in proper form for allowance and such action is earnestly solicited.

Claims 13-17 and 28 depend either directly or indirectly from independent claim 10 and further define a microfluidic device not shown or suggested in the art. It is believed that claims 13-17 and 28 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Referring to claim 18, a method is provided for monitoring the environment within the microfluidic device. The method includes the steps of mixing a dye in a prepolymer mixture in providing the same as a pregel. Thereafter, the pregel is injected in the channel within a microfluidic device and polymerized in the channel to form a monitor structure. The fluid is passed over the monitor structure in the channel such that the dye changes color in response to a parameter of the fluid having a predetermined value.

As heretofore described with respect to claim 10, nothing in any of the cited references shows or suggests the steps of mixing the dye into a prepolymer mixture and injecting the prepolymer mixture to a channel of a microfluidic device to be polymerized. Such a

methodology is entirely absent from the cited references. As previously noted, the '422 application merely discloses the binding of a receptor that senses the changes in pH in a fluid sample to a polymer resin. The '852 patent does not disclosure a pre-polymer mixture or polymerization of such a mixture as required by claim 18. Finally, while the Beebe et al. '872 patent discloses a hydrogel that expands and contracts in response to exposure to a fluid having a predetermined parameter such as the value of pH, the '872 patent does not teach or contemplate mixing a dye in a pre-polymer mixture and providing the same as a pregel; injecting the pregel into a channel of the microfluidic device; or polymerizing the pregel in the channel to form a monitor structure, as required by claim 18. Consequently, it is believed that independent claim 18 defines over the cited references and is in proper form for allowance.

Claims 19-27 depend either directly or indirectly from independent claim 18 and further define a method not shown or suggested in the prior art. It is believed that claims 19-27 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Referring to claim 29, a microfluidic device is defined that provides a visual display in response to a change in a predetermined parameter of the fluid flowing therethrough. The microfluidic device includes a body defining a channel for accommodating the flow of fluid therethrough. A monitor structure is retained in the channel of the body at a user-desired position within the flow of fluid. The monitor structure has a color. An immobilized dye is entrapped within the monitor structure. The dye changes the color of the monitor structure in response to a change in the predetermined parameter of the fluid. The monitor structure includes a polymerized mixture. In addition, the immobilized dye is a first color in response to the predetermined parameter of the fluid having a first value and a second color in response to the predetermined parameter of the fluid having a second value.

As heretofore described, nothing in the cited references shows or suggests providing a monitor structure within a channel of a microfluidic device wherein:

1) the monitor structure includes an immobilized dye entrapped therein; or
2) the immobilized dye is entrapped within a monitor structure that includes a polymerized mixture.

As previously noted, the '422 application merely discloses the binding of a receptor that senses the changes in pH in a fluid sample to a polymer resin. The '852 patent does not disclose a polymerized mixture or entrapping a die within the polymerized mixture as required by claim 18. Finally, while it is noted that the Beebe et al. '872 patent discloses a hydrogel that expands and contracts in response to exposure to a fluid having a predetermined parameter such as the value of pH, the '872 patent does not teach or contemplate entrapping a dye within a polymerized mixture. As such, it is believed that independent claim 29 defines over the cited reference and is in proper form for allowance.

Claims 31-36 depend either directly or indirectly from independent claim 29 and further define a microfluidic device not shown or suggested in the prior art. It is believed that claims 31-36 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Applicant believes that the present application with claims 10, 13-29 and 31-36 is in proper form for allowance and such action is earnestly solicited. Applicant believes that no additional fees are required in connection with the present submission. However, the Director is hereby authorized to charge payment of any other fees associated with this communication or credit any overpayment to Deposit Account No. 50-1170.

Respectfully submitted,

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